K00 3946

FEB 2 7 2001

GE Medical Systems

P.O. Box 414, W-709
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY AND EFFECTIVENESS

- This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- Identification of Submitter
  Larry A. Kroger, Ph.D., 414-544-3894, December 13, 2000

- Identification of the Product
  Signa SP 0.5T Rotating horizontal Body Coil

  Manufactured by: GE Medical Systems MR Israel
  7 Keren Hayesod St.
  Tirat Hacarmel 39120, ISRAEL

- Marketed Devices

  The Signa SP Body Coil is substantially equivalent to the currently marketed Signa SP Head Coil and the Signa SP Flex Coils.

- Device Description

  The Signa SP 0.5T Rotating Horizontal Body Coil is a Transmit/receive birdcage RF design. It can be rotated around its long axis to allow easy access from the outside.

- Indications for Use

  The Signa SP 0.5T Rotating Horizontal Body Coil provides imaging capability for the Signa SP MR System. The Rotating Horizontal Body Coil is intended for imaging of the Abdomen, Spine, Neck, and extremities.

  Comparison with Predicate

- The Signa SP 0.5T Rotating Horizontal Body Coil is similar to the currently marketed Signa SP Head and Flex Coils except that it covers larger area than the Head Coil and has better uniformity than the Flex Coils

- Summary of Studies

  The Signa SP 0.5T Rotating Horizontal Body Coil was evaluated to the appropriate NEMA performance standards. The Coil was evaluated the IEC 601-1 International medical equipment safety standard and IEC 601-2-33 Particular requirements for the safety of magnetic resonance equipment for medical diagnosis and performed to stated specifications

- Conclusions

  It is the opinion of GE that the Signa SP 0.5T Rotating Horizontal Body Coil is substantially equivalent to the currently marketed Signa SP Head Coil (K942604) and Flex Coils (K964306). This Coil does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2001

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems, Inc.
P.O. Box 414, W-709
Milwaukee, WI 53201

Re: K003946
Signa SP 0.5T Rotating Horizontal Body Coil
Dated: December 20, 2000
Received: December 21, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003946

Device Name: Signa SP 0.5T Rotating Horizontal Body Coil

Indications for Use:

The Signa SP 0.5T Rotating Horizontal Body Coil provides imaging capability for the Signa SP MR System. The Rotating Horizontal Body Coil is intended for imaging of the Abdomen, Spine, Neck, and extremities.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003946